UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,307	10/24/2003	Shalaby W. Shalaby	PC25466A	1484

28523 7590 10/14/2009

PFIZER INC.
PATENT DEPARTMENT
Bld 114 M/S 114
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
10/14/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/693,307	SHALABY ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of Applicant's Arguments/Remarks and amended claims filed on 06/03/09 is acknowledged.

Claims 1 and 11 have been amended.

Claims 2-3 and 13 remain cancelled. Claims **1 and 4-12** are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 4-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "50% ionically bonded together to form said liquid conjugate". The rationale behind this limitation is not clear to the examiner because claim 1 requires liquid polymer and basic drug which are ionically bonded together. Since the liquid polymer and basic drug are ionic in nature, it is obvious that the reaction will be in **equimolar ratio** which is inconsistent with the claimed limitation of 50% ionically bonded together. The claim is thus indefinite.

Response to Arguments

4. Applicant's arguments filed 06/03/09 have been fully considered but they are not persuasive.

Applicant argues that the instant specification describes very clearly that the composition comprising the bioactive agent and the liquid polymer wherein at least 50 percent of interaction between the moieties are ionically bonded. Therefore, the phrase is complete within its meaning.

Applicant's arguments are not persuasive because by giving broadest reasonable interpretation to claims, it is the position of the Examiner that claims as recited read as 50% ionically bonded. The claims do not recite any specific duration of time or the claim is not explicit in reciting that the two moieties (polymeric and basic moieties) are mixed till 50% of interaction takes place. The claim recites the limitation as said basic and liquid polymer being at 50 % ionically bonded which makes the limitation ambiguous. It is to be reminded that claims are interpreted in light of specification but the limitations are not imported from specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1 and 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby to (U.S. Patent No. 5,714,159) in view of Kim et al. to (U.S. Patent No. 6,232,304 B1).

Shalaby discloses a hydrogel-forming, self-solvating, absorbable polyester copolymers capable of selective, segmental association into a compliant hydrogel mass on contact with an aqueous environment (abstract). According to Shalaby, the copolymer comprises a base component, designated as "Component A". The "Component A" refers to the basic structure of the copolymers of the invention. "Component A" comprises a molecular chain having a hydrophilic block "Y" and a relatively hydrophobic polyester block "X". The hydrophobic block/segmented polymer comprises a polyester formed by grafting a glycolide, lactide, .epsilon.-caprolactone, p-dioxanone, trimethylene carbonate or combinations thereof, onto the hydroxylic or amino groups of a hydrophilic polymer precursor. The hydrophilic block comprises a polyoxyethylene, Poly (oxyethylene-b-oxypropylene), polypeptide polyalkylene oxamate, a polysaccharide, and derivatives thereof; or a liquid, high molecular weight polyether glycol interlinked with an oxalate or succinate functionalities in linear or branched form (column 6 and 7, lines 65-67 and 1-15).

"Component A" optionally comprises carboxylic end groups which facilitates ionically binding a bioactive agent or drug (column 7, lines 19-23). The composition comprises an absorbable carrier which helps in immediate and

controlled release of the bioactive drug (column 7, lines, 30-33).

According to Shalaby a copolymer optionally comprises a bioactive agent; such a copolymer is capable of the controlled-release of a biologically active agent for modulating cellular events such as wound healing and tissue regeneration (column 6, lines 30-45). The copolymer described by Shalaby is capable of being injected into living tissues (column 6, line 57) (hence proving that the copolymer is liquid conjugate). The hydrophobic block "X" as described above refers to absorbable polyester chain block(s) or segment(s) of variable length, which is a viscous liquid at room temperature. These hydrophobic block (s)"X "comprises, copolymeric segments of glycolide, l-lactide, trimethylene carbonate (column 8, lines 4-9).
The "Hydrophilic Block(s)" or segment (s) "Y" comprises poly (oxyethylene) (column 8, lines 17-18).

Shalaby further discloses that the length of the hydrophilic block "Y" and its weight fractions can be varied to modulate the rate of gel formation, its modulus, its water content, and diffusivity of bioactive drug (column 8, lines 23-37). Shalaby discloses that to render "Component A" more receptive to basic drugs, its end-groups can optionally be carboxylated (column 10, lines 1-5). "Component A" can be succinylated to provide acidic end-groups for ionic binding on the bioactive agent/drug (column 12, lines 8-10).

Shalaby further discloses that liquid compositions made of component A with or without drug or bioactive agent can form hydrogels upon contacting a liquid environment (column 12, lines 10-12). The "Component A" as disclosed in the reference, comprises an inherent viscosity at 25 degrees C in chloroform ranging between 0.03 to 0.80 dL/g and can be present as a liquid at room temperature and can be administered through a syringe needle (column 10, lines 10-17). The liquid conjugate, "Component A" in this case can combine with bioactive drugs such as calcium (column 12, lines 58-59) hence proving the ionic bond linkage between the liquid conjugate and the bioactive drug.

Shalaby does not specifically teach the bioactive agent such as Ziprasidone (aryl- heterocyclic compound).

Kim et al. teaches aryl- heterocyclic drug such as Ziprasidone. Kim et al. discloses that increasing drug solubility and stability through appropriate formulation can lead to therapeutic efficacy of the drug (column 1, lines 17-20). On (column 3, lines 10-27), Kim et al. discloses that ziprasidone has utility as a neruleptic drug, and is thus useful as neuroleptic/antipsychotic drug (column 3, lines 26-30). It is due to this utility of ziprasidone, it would have been obvious to one of ordinary skilled in the art at the time the invention was made to utilize Ziprasidone in the liquid conjugate as a bioactive drug or alternately to use polymers and carboxyl-bearing polymers or carboxyl-bearing block/segment as forwarded by Shalaby, with Ziprasidone to make liquid conjugate because Ziprasidone acts as an antipsychotic as disclosed my Kim et al. Additionally, since Ziprasidone happens to be basic in nature, it would be expected for ziprasidone to

form ionic bond with carboxyl-bearing polymers or block/ segment copolymers which are acidic in nature. A skilled artisan would thus have been motivated to formulate a liquid conjugate comprising Ziprasidone and absorbable polymer with one or more carboxyl group with a reasonable expectation of success.

Response to Arguments

7. Applicant's arguments filed 06/03/09 have been fully considered but they are not persuasive.

Applicant argues that Shalaby does not teach liquid conjugate. Shalaby teaches conjugates which form hydrogel mass on contact with aqueous environment. Applicant further argues that Shalaby does not teach the polymers of claim 1 and the examples of instant specification do not form gel and remain essentially liquid when contacted with aqueous environment as opposed to prior art's gel formulation. Applicant further asserts that claim 1 recites various polymers and applicants are not required to provide examples with each and every polymer.

Applicant's arguments are not persuasive because contrary to Applicants assertion Shalaby does teach liquid conjugates. As discussed in the rejection above, Shalaby teaches polyester carbonate disclosed as component A which is made up of hydrophobic and hydrophilic blocks. The hydrophobic block"X" refers to absorbable polyester chain block(s) or segment(s) of variable length, which is a viscous liquid at room temperature. Shalaby teaches that the hydrophobic block (s)"X "comprises, copolymeric segments of glycolide, l-lactide, trimethylene carbonate) and the hydrophilic block comprises polyoxyethylene in column 8, lines 4-9 which reads on the claimed

polymer that is polycarbonate. Additionally, Shalaby discloses that "Component A" possesses an inherent viscosity at 25 degrees C in chloroform ranging between 0.03 to 0.80 dL/g and can be present as a liquid at room temperature and can be administered through a syringe needle (column 10, lines 10-17) thereby proving that the conjugate is liquid. Further more, in reply to applicant's arguments that Shalaby does not teach liquid conjugate, the Examiner points to column 6, line 57 of Shalaby where the reference discloses that the polymer is capable of being *injected* into living tissues (column 6, line 57).

In response to Applicants arguments that Shalaby forms a gel when in contact with an aqueous environment, the Examiner points out that instant claim as recited do not pose the limitation that liquid polymers shall not form any gel once contacted with an aqueous environment. While it is true that the prior art's polymer forms a gel in aqueous environment, the reference also teaches that the polymeric composition can be injected and hence is liquid. The Examiner respectfully points out that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612